

Your Drug Eluting Stent Procedure

How Do I Prepare for My Procedure?

In the days prior to your treatment, make sure you:

- Take all of your prescribed medicines
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin and/or Plavix®
- Make sure your doctor knows about any allergies you have
- Refrain from eating and drinking after midnight on the night before your treatment
- Follow all instructions given to you by your doctor or nurse

You may be given a mild sedative to help you relax, but you will not be put to sleep. There are two reasons for this. First, most people find they experience little to no discomfort from the procedure. Secondly, your doctor may need to ask you to take a

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Your Drug Eluting Stent Procedure (continued)

deep breath while X-rays are being taken, to improve the quality of the pictures.

The procedure usually lasts about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable, but you may feel some pressure or chest pain when the balloon is inflated. This is normal and will quickly fade when the balloon is deflated.

Your Drug Eluting Stent Placement Procedure

Your procedure will be performed in a cardiac catheterization laboratory (cath lab). You will lie on the X-ray table, and an X-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small, sticky patches to your chest and using a specialized ECG recorder and monitor.

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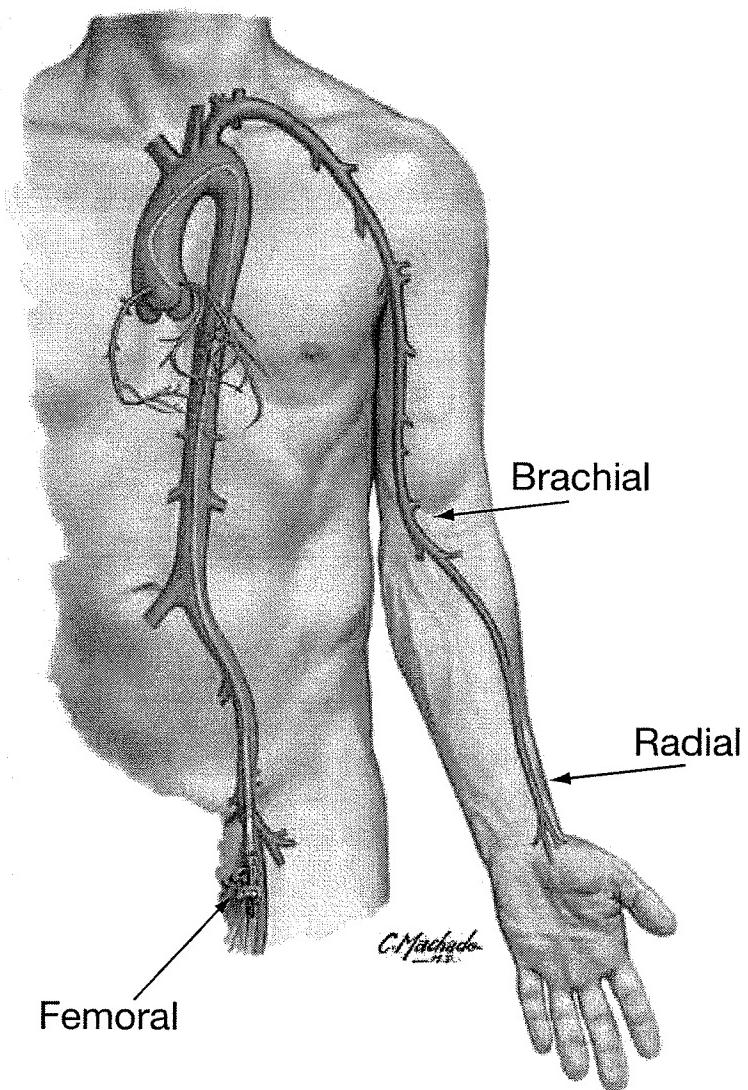
Your Drug Eluting Stent Procedure *(continued)*

The groin is the most common site for catheter introduction and requires a very small skin incision to be made on the inside of your upper thigh. The area will be shaved and cleaned with an antiseptic, and you will be given a local anesthetic to numb the area. This incision will allow an introducer sheath (short tube) to be inserted into your femoral artery (the main artery of the thigh, supplying blood to the leg). Your doctor will then insert a guiding catheter (long, flexible tube) into the introducer sheath and advance it to where the coronary arteries branch off to the heart. A guide wire is then advanced through the guiding catheter to the narrowing in the coronary artery. This helps carry all the necessary devices required during the stenting procedure.

Additional options for catheter introduction are the arm/brachial approach (incision is made on the inside of your elbow) and the wrist/radial approach (incision is made on the inside of your wrist).

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Your Drug Eluting Stent Procedure *(continued)*



Blood vessel access for heart catheterization through the femoral, radial or brachial artery

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Your Drug Eluting Stent Procedure *(continued)*

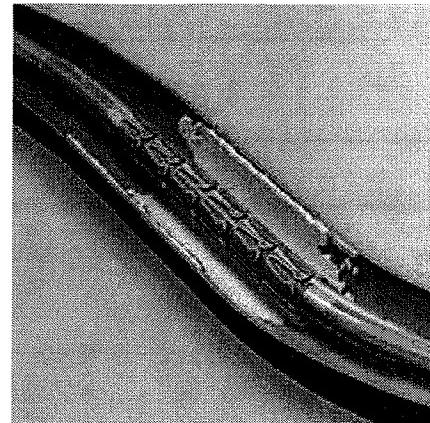
After the catheters are inserted, your doctor will inject a contrast dye through the guiding catheter into your artery to view the narrowing. Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being taken, your doctor may ask you to take a deep breath and hold it for a few seconds. You may also be asked to cough after the X-ray picture is completed to help speed the removal of the contrast dye from the arteries.

Using the guiding catheter, a balloon catheter is positioned in the narrowing in the coronary artery and the balloon is then inflated. This compresses the plaque and widens the coronary artery. This procedure is called pre-dilatation.

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Step 1:

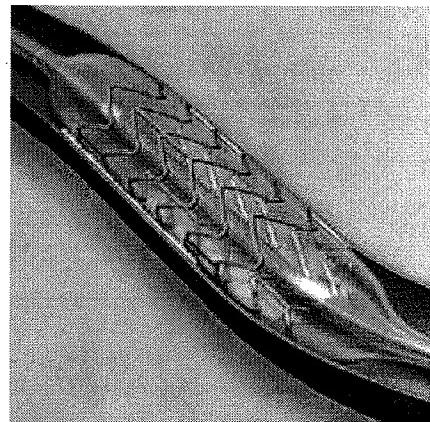
The stent mounted on a balloon catheter is delivered to the narrowing in the coronary artery by a delivery catheter.



Step 1

Step 2:

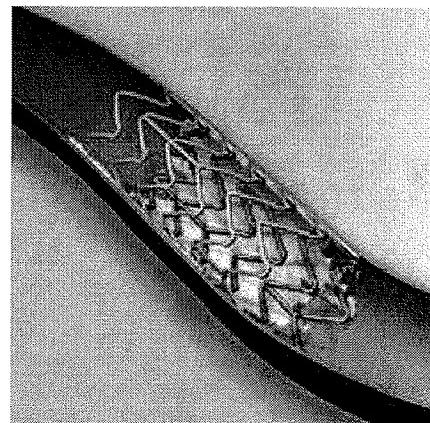
The balloon is then inflated and this expands the stent, pressing it against the coronary artery wall. Your doctor may choose to expand the stent further by using another balloon so that the stent can make better contact with the artery wall. This is known as post-dilatation.



Step 2

Step 3:

Once in place, the XIENCE V stent will remain as a permanent implant in your coronary artery.



Step 3
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Your Drug Eluting Stent Procedure

(continued)

Immediately after Procedure

You will be asked to lie flat for four to six hours following the procedure and to not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure will also be placed on the area.

A vascular closure device may be used to seal the incision site in your groin or arm. You will be allowed to get up and walk around sooner if this type of device is used. Your hospital stay may range from one to three days.

Medications will be prescribed for you before and after stent placement. Antiplatelet medications such as aspirin and Plavix® are the most commonly prescribed. They help prevent a blood clot (thrombus) from forming and blocking the stent lumen. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

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Your Drug Eluting Stent Procedure *(continued)*

CAUTION: If you have any chest pain, or discomfort or bleeding from your incision site, call your doctor immediately. If your doctor is unavailable, call for an ambulance to take you to the nearest hospital emergency room.

Take All Medications as Instructed

After you leave the hospital, your cardiologist will instruct you to take a daily dose of aspirin and another antiplatelet drug such as Plavix®. Your doctor will tell you how long you should continue taking the antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructs you:

- Follow your medication schedule exactly to avoid possible complications after you receive your stent. Do not miss any doses.
- Call your doctor if you cannot keep taking your medications because of side effects such as rash, bleeding, or upset stomach.

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Your Drug Eluting Stent Procedure *(continued)*

- **CAUTION:** Do not stop taking your prescribed medications unless you are instructed to do so by the doctor who performed your stent procedure.
- **CAUTION:** Notify your cardiologist or family doctor if you are scheduled to see the dentist while on antiplatelet medication. Your doctor may prescribe antibiotics to avoid the potential of an infection. You should review with your doctor any recommendations from your dentist to stop your prescribed medications.
- **CAUTION:** Before undergoing implantation of a drug eluting stent, if you plan to have any type of surgery, which may require you to stop taking antiplatelet medications, you and your cardiologist should discuss whether or not placement of a drug eluting stent is the right treatment choice for you.

If surgery or dental work, which would require you to stop taking antiplatelet medications, is recommended after you've received the stent, you and your doctors should carefully consider the risks and benefits of this surgery or dental work versus the possible risks from early discontinuation of these medications.

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Your Drug Eluting Stent Procedure *(continued)*

If you do require discontinuation of antiplatelet medications because of significant bleeding, your cardiologist will carefully monitor you for possible complications. Once your condition has stabilized, your cardiologist may put you back on these medications.

Follow-Up Care

You will be discharged to the care of your cardiologist or family doctor. You should be able to return to your normal activities soon.

CAUTION: Notify your doctor immediately if you experience chest pain (angina), or notice any changes such as more severe or frequent chest discomfort, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your coronary arteries.

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Your Drug Eluting Stent Procedure *(continued)*

Your doctor will ask you to return for follow-up visits. The first visit is usually two to four weeks after your stent is implanted, with follow-up visits every six months for the first year. Be sure to keep all appointments for follow-up care, including blood tests.

Keep Your ID Card Handy

CAUTION: Show your identification card if you report to an emergency room. This card identifies you as a patient who has had a stent implanted.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant. Test results indicate that patients with single or overlapped XIENCE V stents can undergo MRI scans safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 720 Gauss/cm or less

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Your Drug Eluting Stent Procedure *(continued)*

- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for 15 minutes of scanning or less

The stent(s) should not migrate in this MRI environment, and MRI may be performed immediately following the implantation of the XIENCE V stent(s). Prior to undergoing an MRI scan, inform your doctor that you have a XIENCE V Everolimus Eluting Coronary Stent.

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Preventing Coronary Artery Disease

Coronary artery disease can be treated effectively, but it has no cure. You can help to prevent your coronary artery disease from progressing by carefully following your doctor's advice. Your doctor may prescribe medications to help control your blood pressure, diabetes, and/or high cholesterol. Your doctor may also recommend some lifestyle changes. Among the healthy choices you can make:

Stop smoking. If you smoke, quitting is the single most important thing you can do to lower your risk of coronary artery disease. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. And smoking increases your heart rate and blood pressure, raising your risk of heart attack and stroke. If you're ready to quit, ask your doctor for advice — he or she can recommend smoking cessation aids to help you quit.

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Preventing Coronary Artery Disease (continued)

Increase your activity and eat a healthy diet. A sedentary lifestyle increases your risk. Your doctor can recommend an activity program tailored for your situation. Regular exercise can help you lower your blood pressure and blood cholesterol and reach a healthy weight. It can also help you manage the daily stresses of modern life more easily. Choose a healthy diet. A diet low in saturated fats and cholesterol and rich in lean protein, fresh fruits, vegetables and whole grains, can help you achieve a healthy weight and control your blood pressure, and cholesterol levels.

Manage your stress. Stress is an inescapable aspect of modern day living, but you can help lessen its negative health effects by practicing the “relaxation response.” Research has shown that relaxation techniques can improve your ability to cope with stressful events while decreasing your heart rate, blood pressure, and stress hormone levels.

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Frequently Asked Questions

How long will the stent stay in my body?

Stents are designed to stay in your body permanently.

What are the restrictions or cautions after I've received a stent?

If you require magnetic resonance imaging (MRI), tell your doctor or MRI technician that you have an implanted stent.

When can I resume my regular activities?

Your doctor will advise you. Many patients can return to work and follow their normal routine about a week after their stent procedure.

Will my stent set off the metal detector at airport security checkpoints?

No, your stent implant will not trigger alarms at security checkpoints.

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Frequently Asked Questions *(continued)*

Will I be able to feel the stent inside me?

No, you will not be able to feel the stent once it has been implanted in your artery.

Could I have recurring symptoms?

Yes, it is possible that you will experience symptoms again, either due to a new blockage in the region treated with the stent or a blockage at another place in your coronary arteries. Your doctor will monitor your progress.

How can I help prevent a recurrence of symptoms?

While there is no sure way to prevent a recurrence of symptoms, you can reduce the risk through exercise, not smoking, and eating a healthy diet. Your doctor can advise you about lifestyle changes.

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Definition of Medical Terms

Angina: Chest pain caused by inadequate supply of blood to the heart.

Angioplasty (also referred to as PTCA): A minimally invasive procedure in which a balloon dilatation catheter is passed through to the blocked area of an artery. Once inflated the catheter compresses the plaque against the blood vessel wall and enlarges the vessel opening. An angioplasty can also be performed with placement of a stent.

Anticoagulant: A medication to prevent or slow the clotting of blood.

Antiplatelet: A substance to reduce clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Atherosclerosis: A disease that causes narrowing or blockage of arteries caused by a build-up of fat

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Definition of Medical Terms

(continued)

(cholesterol) within the artery wall. The build-up is sometimes referred to as “plaque.”

Cardiac Catheterization Laboratory (Cath Lab): A sterile X-ray theater in which heart catheterization is performed.

Catheter: A thin, hollow, flexible tube used to access the coronary arteries during an angiogram or during an angioplasty procedure. This catheter can be used to inject medication, fluids, or contrast dye during your procedure. Catheter is also used to describe the device used to deliver the balloon or stent during an angioplasty procedure.

Coronary Angiography (or Heart Catheterization or Cardiac Cath): A test in which contrast dye is injected to create images of the coronary arteries and the chamber of the heart. This allows the doctor to see the extent of the disease in the coronary arteries and make a decision on how to best treat the blockages.

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Definition of Medical Terms *(continued)*

Coronary Arteries: The blood vessels that carry oxygenated blood from the aorta to the heart muscle. There are four major coronary arteries: the left main, the right coronary artery, the left anterior descending, and the circumflex.

Coronary Artery Bypass Graft Surgery (CABG): Open-heart surgery to treat CAD.

Coronary Artery Disease (CAD): The formation of blockages or atherosclerotic plaques within coronary arteries that result in restricted blood flow to the heart muscle.

Electrocardiogram (ECG/EKG): A test that records changes in the electrical activity of the heart. An ECG/EKG may show whether parts of the heart muscle are damaged due to decreased blood flow to the heart muscle.

Femoral Artery: The main artery of the thigh, supplying blood to the leg.

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Definition of Medical Terms *(continued)*

Fluoroscope: An X-ray device that creates an image of the body that can be viewed on a TV monitor. This permits the doctor to obtain real-time images of the internal structures of a patient.

In-stent Restenosis: Recurrent blockage or narrowing of a previously stented vessel.

Local Anesthetic: A substance used to numb the area to which it is applied.

Lumen: The inner channel or cavity of a vessel or tube. In a blood vessel, it is the opening through which blood flows.

Myocardial Infarction (MI): Also called a heart attack. Permanent damage of an area of the heart tissue, due to interruption in the blood flow to the heart muscle (myocardium).

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Definition of Medical Terms *(continued)*

Magnetic Resonance Imaging (MRI): A non-invasive diagnostic procedure used to obtain images of internal body structures through the use of magnets and radio waves.

Percutaneous: Performed through the skin.

Plaque: An accumulation or build-up of fatty deposits, calcium, white blood cells, and other substances in the wall of an artery that results in narrowing of the vessel lumen.

Restenosis: A recurring blockage caused by the excessive growth of scar tissue inside the artery or stent, following an interventional procedure such as angioplasty.

Stent: A metallic mesh tube that is implanted into an artery during an angioplasty, providing a scaffold to help hold the artery open, ensuring blood flow to the heart muscle.

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Definition of Medical Terms

(continued)

Transluminal: Through the inside opening of a vessel or artery.

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Abbott Vascular
Santa Clara, CA 95054-2807
USA
TEL: 1.800.227.9902
FAX: 1.800.601.8874

Abbott Vascular
Manufacturing Facility
26531 Ynez Road
Temecula, CA 92591
USA
TEL: 1.800.227.9902
FAX: 951.914.2531

Abbott Vascular Japan
Co., Ltd.
3-5-27 Mita,
Minato-Ku, Tokyo, JAPAN
108-6304
Tel: 81 03.4560.0801

Abbott Vascular
International BVBA
1831 Diegem
BELGIUM
Tel: + 32.2.714.14.11
Fax: + 32.2.714.14.12

This product is intended for use by or under the direction of a physician. Prior to use, it is important to read thoroughly the instructions for use, warnings, and potential complications associated with the use of this device.

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THE CYPER® SIROLIMUS-ELUTING CORONARY STENT

Patient Information for the CYPER® Sirolimus-Eluting Coronary Stent (SY-fer sir-AHL-i-mus e-LUT-ing KOR-o-nair-e stent)

This summary is about the CYPER® Sirolimus-eluting Coronary Stent, a combination product consisting of a device (stent) and an anti-rejection-type medication (sirolimus) contained in a polymer (soft plastic) coating on the stent. Please read it carefully. This information should not take the place of careful discussions with your doctor. Only your doctor can decide if the CYPER® Stent is right for you. Contact your doctor if you have any questions.

WHAT IS THE CYPER® STENT?

The CYPER® Stent has three parts:

The stent: a small, expandable, slotted metal tube that is inserted into a coronary artery (one of the blood vessels that supply the heart with oxygen and nutrients). A stent acts as a scaffold that helps hold the artery open, which allows blood flow to the heart and relieves symptoms caused by the blockage.

The anti-rejection-type medication (sirolimus): an anti-rejection-type medication that limits the overgrowth of tissue as the healing process occurs following coronary stent implantation.

The inactive ingredient: a polymer (soft plastic) coating on the stent that contains the medication sirolimus, and slowly elutes (releases) the medication into the artery wall around the stent.

HOW DOES THE CYPER® STENT WORK? Overgrowth of tissue is believed to be a major factor responsible for re-narrowing of the artery after stent placement. The CYPER® Stent limits this overgrowth of tissue, which significantly reduces the chance of re-blockage and the need for another procedure.

WHAT IS THE CYPER® STENT USED FOR? The CYPER® Stent is used to help open coronary arteries in people who have symptoms of ischemic disease (lack of blood flow to the heart) such as heart attack or angina, due to atherosclerosis (fatty substances such as cholesterol deposited on the inner lining of blood vessels). Placement of the CYPER® Stent is no different than the placement of a bare-metal (uncoated) stent. The CYPER® Stent will remain in the vessel permanently.

WHO SHOULD NOT RECEIVE THE CYPER® STENT?

Patients who:

- are allergic to the anti-rejection-type medication (sirolimus)
- are allergic to the polymers used in the coating
- cannot take antiplatelet medication such as aspirin
- cannot take anticoagulant medication (blood thinners)
- have a blockage that the doctor decides will not allow complete inflation of the angioplasty balloon
- Women of childbearing age should be using effective contraception before they receive the CYPER® Stent, and for 12 weeks after. Women who are nursing should discuss this with their doctor before receiving the CYPER® Stent.

The CYPER® Stent has not been studied for use in children.

WHAT OTHER MEDICAL ISSUES SHOULD I DISCUSS WITH MY DOCTOR? You should tell your doctor about any other medications (prescription or nonprescription) you are taking, especially medications that affect your immune system. You should also tell your doctor if you have a history of bleeding problems.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF THE CYPER® STENT? Use of the CYPER® Stent carries the risks associated with all coronary stent placement, including allergic reaction, irregular heart rhythm, stent thrombosis (blood clot in the stent), death, reactions to antiplatelet or anticoagulant medications or to dyes used during placement, emergency bypass surgery, fever, bleeding at the puncture site, chest pain or angina and stroke. The risk of thrombosis with any stent, uncoated or drug-eluting, remains low. Our two clinical trials following patients over a five-year period indicate a similar overall risk of thrombosis between the CYPER® Stent and uncoated stents. However, after 1 year, a very small increased risk of stent thrombosis can be seen with the CYPER® Stent versus uncoated stents.

Potential adverse events which may be associated with the implantation of a coronary stent include: allergic reaction, irregular heart rhythm, death, drug reactions to blood-thinning agents or contrast media, emergency bypass surgery, fever, bleeding at the puncture site, chest pain or angina, and stroke. Potential adverse events related to the drug sirolimus (based on studies of patients who used the drug orally for a prolonged period of time) include: infection, tumor formation, fatigue, joint pain and diarrhea.

Exposure to sirolimus and the polymer coating on the CYPER® Stent is directly related to the number of implanted stents. Use of more than two CYPER® Stents has not been adequately evaluated. Use of more than two CYPER® Stents will result in your exposure to a larger amount of sirolimus and polymer coating than experienced in the clinical studies.

WHAT CAN I EXPECT AFTER I RECEIVE THE CYPER® STENT? Many patients are able to return home the day following their procedure. Your doctor will decide how long you need to stay based on your individual needs. Your doctor will prescribe aspirin, and other antiplatelet or anticoagulant medications (blood-thinners). It is very important that you take these medications exactly as directed; be sure not to miss any doses. Call your doctor if you feel that you cannot tolerate your medications or develop any side effects such as bleeding, upset stomach, rash or itching, or if another healthcare professional asks you to stop taking your medication. You may also have to have follow-up blood tests to monitor the effects of the CYPER® Stent.

You should be able to return to your normal activities such as work, sports and sex very soon, but again, this will be determined by your doctor. Check with your doctor prior to doing anything that is physically strenuous. You will be given a schedule for follow-up visits with your cardiologist or family doctor, and a small identification card to carry with you at all times, containing information about the CYPER® Stent.

If you have chest pain after your procedure, see a doctor immediately.

HOW CAN I GET MORE INFORMATION ABOUT THE CYPER® STENT? If you have any other questions, speak to your doctor, or call 1-800-781-0282 or visit www.cypherausa.com

Sirolimus-eluting Stent made by Cordis Corporation pursuant to a license from Wyeth Pharmaceuticals.

Rapamune® is a trademark of Wyeth Pharmaceuticals.

†Sirolimus is also available in tablet and liquid form, known by the name Rapamune®. Let your doctor know if you are currently using this medication.

Cypher®

Sirolimus-eluting Coronary Stent

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